

**ORTHOSPEC™**  
Extracorporeal Shock Wave Therapy (ESWT)

**Patient Information**



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*Your Partner in Shock Wave Therapy*

**Date of Print:** March 28, 2005

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**Date of Print:** March 28, 2005



## Orthospec™ ESWT for the Treatment of Proximal Plantar Fasciitis

### Patient Information

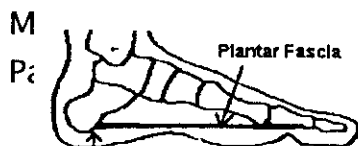
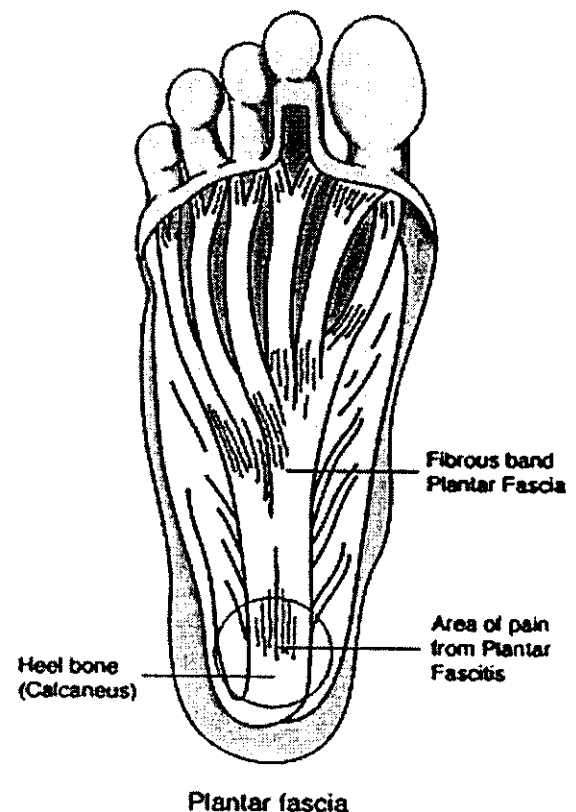
#### *What is Extracorporeal Shock Wave Therapy (ESWT)?*

Extracorporeal means "outside the body". Extracorporeal Shock Wave Therapy is a treatment method that applies acoustic or "sound wave" energy to the heel tissue from outside the body. The Orthospec™ device is intended to apply shock waves to the heel tissue of patients who have experienced symptoms of Proximal Plantar Fasciitis for six months or more and who have not responded to conservative therapies such as medications, splints, or physical therapy. ESWT is the same shock wave technology that has been successfully used to fragment kidney stones (lithotripsy).

#### *What is Plantar Fasciitis?*

Proximal Plantar Fasciitis is the inflammation (irritation or injury to tissues) of the plantar fascia. Proximal means nearer to the heel of the foot. The plantar fascia is a tight band of fibrous tissue which begins at the heel, travels across the arch, and ends at the ball of your foot. The inflammation (irritation or injury to tissues) and pain is most often felt at the inner part of the heel and may extend into the arch.

The most common symptom is pain after rest, referred to as Post-Static Dyskinesia (i.e. pain when you first rise in the morning). Plantar Fasciitis often



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resolves after conservative care prescribed by your physician. However, extracorporeal shock wave therapy is given to those patients who have chronic pain and who have failed the more conventional or established therapies.

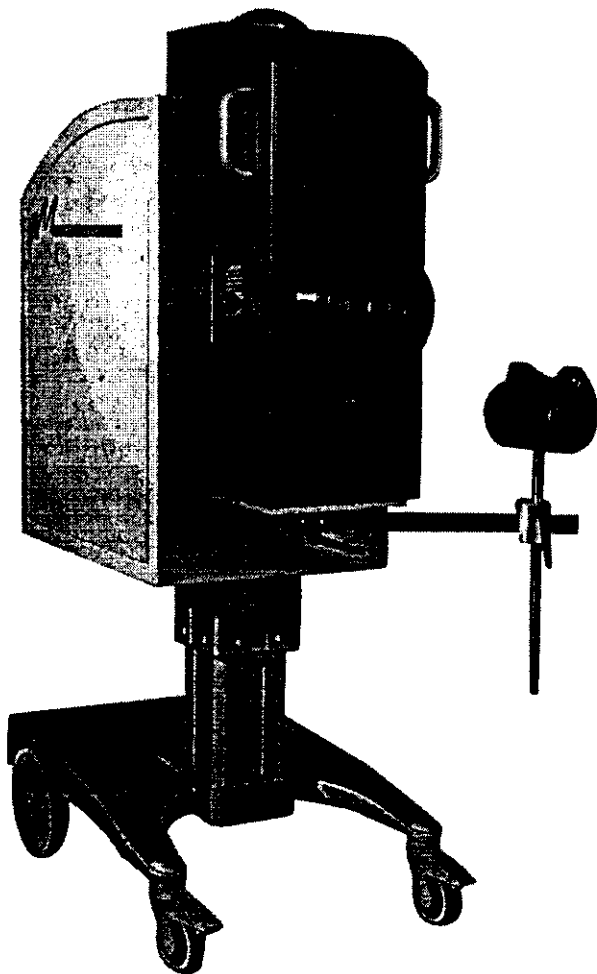
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### *What are the Available Alternative Therapies?*

There are several standard treatments for heel pain. In some cases of extremely chronic pain, surgery may be necessary. Standard therapies recommended are:


- Rest
- Ice
- Physical therapy
- Orthotics (shoe inserts, tape, arch support)
- Night splints
- Over-the-counter pain relievers
- Non-steroidal anti-inflammatory medications (medications to suppress inflammation and pain – i.e., Ibuprofen, Naprosyn, Dextra)
- Steroid injections



### *What is the Orthospec™ ESWT Device?*

The Orthospec™ ESWT device is a non-invasive alternative method intended to treat Proximal Plantar fasciitis, with or without bony growths on the heel (heelspur). The device applies extracorporeal shock wave energy to the heel tissue. The shock wave is generated within a reflector chamber and transmitted through a water-filled contact membrane (blue rubber membrane) to the treatment site. The reflector chamber is a hollow compartment that gathers sound waves and directs them to the target

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heel tissue.

The Orthospec™ therapy is an outpatient procedure that lasts up to 25 minutes for a single session.

*When seeking a treatment center that provides Orthospec™ ESW therapy, make sure that the center is properly supervised by a trained certified physician who specializes in the care of patients with Plantar Fasciitis.*

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### *Who Should Have ESW Therapy for Proximal Plantar Fasciitis?*

ESWT with the Orthospec™ device is geared to patients 18 years of age or older who have heel pain, caused by Plantar Fasciitis, for 6 months or more and who have tried the conservative therapies but were unsuccessful in relieving pain.

### *Who Should Not Have ESW Treatment for Proximal Plantar Fasciitis?*

- Patients with open or active bone growth centers (can be used when bone growth is complete);
- Patients who have a known or suspected malignancy (cancer) in the treatment area;
- Patients who have an insufficient blood supply to the area of the body to be treated (peripheral vascular disease);
- Patients who are known to have coagulation (blood clotting) disorders or are taking anti-coagulant medications to prevent clotting of the blood;
- Patients with infection in the area to be treated;
- Patients with an allergy to latex or the coupling solution used in the procedure

### *What are the General Warnings and Precautions?*

#### *Warnings*

1. Patients who are currently undergoing anticoagulation therapy (preventing the clotting of blood) or taking other medications that might prolong bleeding time (i.e., aspirin) should consult with their physician regarding temporary discontinuation of such medications before beginning treatments to prevent potential bruising and blood collections around the treatment area.
2. The safety and effectiveness of the Orthospec™ in the treatment of children has not been demonstrated. Studies indicate that there are growth plate disturbances in the epiphyses (growing portion) of developing long bones in



rats subjected to shock waves. The significance of this finding in humans, however, is unknown.

### *Precaution*

1. It is recommended that there be no less than a one month interval between treatments and not over 4 treatments in a session. The number of shock waves per session should not exceed 3,800. As the clinical study has shown, patients' relief of pain should continue for up to 3 weeks after a treatment session. Therefore, a one month time window between treatments is recommended.
2. The safety and effectiveness of this procedure in patients who are pregnant, who are under 18 years of age, or have had prior surgery for proximal plantar fasciitis have not been established.

To prevent unnecessary risks, these warnings should be seriously considered. If you have any additional questions regarding the above, consult your physician.

### *What are the Side Effects and Complications?*

During the Orthospec™ clinical study of 172 patients, three cases of adverse reactions were reported. They included two cases of bruising and one case of mild local swelling. Discomfort at the treatment site was also noted by some patients during the procedure. None of the adverse reactions were severe, and none required medical intervention or subsequent medical care.

Potential risks and complications that were not seen in the clinical study with this device include:

- Rare allergic or sensitive reaction to the coupling solution applied to skin during treatment, or to the Latex membrane. Please inform the physician if you have any knowledge of Latex allergy (this is a rare occurrence).







- Abnormal sensations such as numbness or tingling.
- Tendon rupture
- Pain
- Petechia
- Superficial hematoma

### *What to Expect When Being Treated With the Orthospec™?*

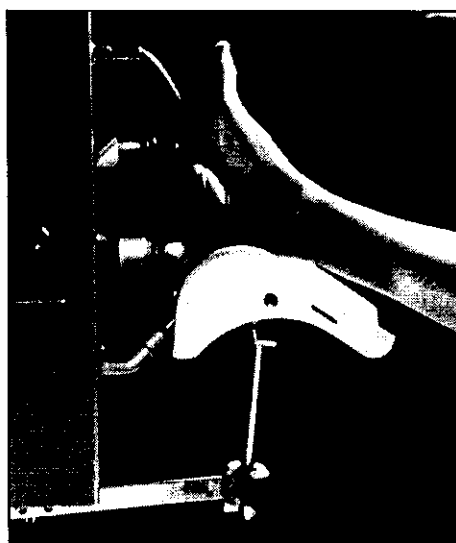
Before your ESW treatment, your physician will ask you to come to the clinic or hospital to discuss your condition and conduct a preliminary screening of your heel pain. The medical staff may take your vital signs such as blood pressure, temperature, and pulse as standard evaluations.

During treatment you will be comfortably positioned by a trained medical professional. Your foot will be placed in the appropriate position. You will probably not need any anesthesia, or sedation (anti-anxiety) medicines during your treatment, however, the session may be uncomfortable. It will be the physician's discretion whether these medicines are necessary. Make sure you relay any concerns or discomfort to your physician while being treated. As the treatment is in session you may feel a pulsating sensation or vibration and hear a loud snapping sound.

Results from the treatment (pain relief) may be immediate or may take some time. After treatment you will be evaluated by your physician again. Your physician may ask you to return 3 weeks or more after your treatment to assess your pain relief.

### Heel Treatment – Patient Positioning

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### *What Are the Results of the Orthospec™ Clinical Study?*

A clinical study was conducted with a total of 172 patients to demonstrate the safety and effectiveness of the Orthospec™ device when treating Proximal Plantar Fasciitis. Patients were divided into two groups: active Orthospec™ treatment group and a placebo treatment group. Patients in the study received one outpatient ESW treatment. A placebo treatment was a false treatment. A piece of foam, which was not visible to the patient, was used in the placebo treatment to block the shock wave from being delivered to the treatment area.

The objective of the study was to demonstrate a significant difference between the active Orthospec™ treatment and the placebo treatment in the following clinical measurements:

- The investigator's (study doctor) assessment of pain Intensity measured by using a Visual Analog Pain Scale (VAS = 0 being no pain and 10 being severe pain);
- The patients' assessment of heel pain upon the first few minutes of walking in the morning;
- The patients' assessment of their improvement of activity and function; and,

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- The use of pain medications taken for heel pain (assess the reduction of pain medications taken at the end of the study).

172 patients were enrolled and randomly assigned to either the active Orthospec™ treatment group or the placebo treatment group. Of the 172 patients the average age was 51 years and the average duration of foot pain was 30 months.

Before treatment, all patients went through pre-testing to determine their initial pain level in an assessment by the investigator and by self-assessment of heel pain. Pain intensity was measured by a 0 to 10 cm scale called the Visual Analog Scale (VAS) and was given a score according to the scale (0 being no pain and 10 being severe pain).

As shown in the table below, at 3 months post-treatment, a significant reduction in heel pain was noted in the Orthospec™ treatment group when compared to the placebo group. A significant reduction of the use of pain medications taken for heel pain was also shown. In each area, the Orthospec™ group had a greater percentage of patient improvement than the placebo group. Of note, patients who received treatments with an energy level setting of 4.5 or less did not appear to receive any benefit from the treatment. Thus, your doctor may wish to terminate your treatment if you are unable to tolerate an energy level setting of higher than 4.5.

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Summary of Effectiveness Results at Three Months		
Measurement	Orthospec™ N=115	Placebo N=57
Investigator's Assessment of Heel Pain Response rate	42.9%	19.6%
Patient's Assessment of Heel Pain		
Mean change from baseline	-3.39	-1.78
Response rate	52.7%	28.6%
Patient's Assessment of Activity and Function Response Rate	64.3%	57.1%
Change in the use of Pain Medication		
Increased	1.0%	11.8%
No change	65.0%	74.5%
Decreased	34.0%	13.7%

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*Who should I ask for more information about the Orthospec™?*

Talk with your doctor openly about the ESW treatment with the Orthospec™ device. He/she will be able to address any of your questions. Your doctor and his medical staff are trained and certified to perform all treatments with the Orthospec™ device. Feel free to request their training certificate.

